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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	Case No. 18-CR-258 EJD UNITED STATES' REPLY IN SUPPORT OF MOTION TO EXTEND DEADLINE BY WHICH TO COMPLY WITH THE COURT'S NOVEMBER 5, 2019, ORDER Date: January 13, 2020 Time: 10 a.m. Courtroom: 4, 5th Floor

The government respectfully submits this reply in support of its Motion to Extend Deadline by Which to Comply with the Court's November 5, 2019, Order ("Motion to Extend").

Defendants' oppositions concede (1) that the Court's November 5, 2019 Order ("Order") required FDA to perform a new, time consuming document re-collection for the term "LDT," (2) ignore the extraordinary efforts FDA and the government have made to produce the requested documents (before and after the Order), and (3) make conclusory claims about prejudice that do not withstand scrutiny.

Reading only the defendants' oppositions, one would think FDA did nothing to produce responsive documents. This is not borne out by the record:

- On June 28, 2019, the Court ordered FDA to "provide the parties with specific information regarding the documents [it] agree[s] to produce or object to producing in response to the document requests made by the Government on behalf of Defendants." ECF No. 84.
- On July 15, 2019, FDA responded: "FDA will produce documents responsive to all six categories" and expressly waived its deliberate process privilege for Theranos-specific documents." ECF No. 89-2 (emphasis in original).
- On July 19, 2019, the Court stated "[b]ased on the parties' representations and the representations of FDA . . . the Court believes that the most effective and timely manner for Defendants to receive the documents is to continue with the current process by which the Prosecution works with FDA and CMS to produce the documents." ECF No. 111 at 4. The Court ordered production by October 2, 2019. *Id.* at 5.
- On September 23, 2019, FDA provided a fulsome update to the parties about its efforts to comply. ECF No. 121-2.
- On October 2, 2019, after a hearing, the Court directed "[a]ll Parties shall meet and confer with FDA . . . regarding Defendants' concerns with [FDA's] productions" and ordered FDA to complete its production by October 25, 2019. ECF No. 134.
- Between August 5 and October 24, 2019, FDA produced approximately 60,000 pages of documents. This is on top of the 40,000 pages of documents FDA produced to DOJ in

the investigation. ECF No. 170-1; Declaration of Marci B. Norton ¶¶ 4 & 7 ("Norton Decl.").[1]

During the meet and confer process ordered by the Court on October 2, it became evident FDA and defendants had significant disputes about the terms and the methods for searching. *See* ECF Nos. 216-3 & 170 at 9-12. Although it was not mentioned in their motion to compel or their "narrow" six categories, the defense argued FDA was required to search all custodians for the term "LDT," whether it was joined with Theranos or not. Categories 2 and 4 require production of "documents . . . regarding *Theranos'* Clinical Laboratory Improvement Amendments ("CLIA") compliance" and "documents . . . regarding the FDA's determination of the type of FDA approval required for *Theranos'* proprietary technology." The additional categories are similarly limited. It is difficult to imagine a material responsive document that does not include the word "Theranos." What's more, searching for LDT as a stand-alone term retrieves news articles, resumes, treatises, statutes, oblique references to the term LDT, and other documents of minimal if any relevance. Searching for LDT at the FDA is akin to searching for "security" at the SEC, "trade" at the FTC, or "summary judgment" in the files of a court. The term "fingerstick," which is employed by hand-held glucose monitor companies and others, raises similar overbreadth issues.

In the November 5 Order, the Court resolved the "LDT" dispute in favor of the defense. Since this finding,[2] the government has worked diligently to comply with the Order. At the request of the government and based on the terms of the Court's Order, FDA is *re-collecting* electronically from 65 custodians – the vast of majority of whom will never see this Courtroom – to ensure the term "LDT" and others are covered. Through extensive negotiations with FDA counsel and defense, the government has eliminated, or substantially reduced, issues with redaction, privilege, trade secret, and confidential commercial information that have slowed FDA's production. And the government has produced nearly

[1] FDA's efforts are further summarized in the attached Declaration of Marci Norton.

[2] Although it respectfully disagrees, the government acknowledges the Court's finding it has knowledge and access to the at-issue documents. The defendants' claim the government is taking a "hands-off approach to documents" (ECF No. 261 at 2 & 6) is simply incorrect and ignores the facts set forth in the supporting declaration. *See, e.g.*, ECF No. 215-1 ¶¶ 2, 4, 10.

140,000 documents (without a single redaction for privilege or other information) since the Court's Order, including those from the email files of 11 of the defendants' 22 most significant custodians.[3]

Unable to dispute any of this, the defendants make vague claims about DOJ's "vast resources," speculate that "[s]urely the United States Government can find a way," and demand DOJ be ordered to "take all necessary steps . . . forthwith" (ECF Nos. 216 at 2, 3; 217 at 2) – all without any meaningful specificity or factual support to contest the government's demonstration that "substantial technological and other limits on FDA's ability to quickly collect documents from its custodians that additional personnel or funds will not address." ECF No. 215 at 7; *see also* Norton Decl. ¶¶ 12-14.

The defendants also insist the timetable required for this exhaustive re-search will compromise the defense's ability to prepare for trial and defend this case, but again, besides reciting the schedule they fail to explain why. The government is not proposing producing all documents on or around April 30, but a rolling production, adding to the 200,000 documents which have already been produced, that will assure the parties that the places reasonably likely to have responsive documents have been searched. Again, only a handful of custodians at FDA will be trial witnesses, many may have the same responsive documents, and many were only tangentially involved in Theranos matters.

Finally, the defendants quibble that the government insufficiently met and conferred about the manual search issue. The government took the defendants at their word that they viewed such a search as "unreliable and inconsistent with standard document collection practices," ECF No. 170 at 10, and "[w]e understand that the search terms will be applied to electronic data collected from each custodian using standard forensic collection techniques, to be sure that the search terms are applied to the entire data set for each custodian (including any storage space that might contain deleted material), and to remove the custodians from the collection process." ECF No. 216-2. Now, they do not even defend the sole case they cited to the Court, or dispute that Magistrates in this District have rejected its reasoning. To the extent they accept a manual search may be performed under guidance or direction of DOJ, the government welcomes the change of heart.

[3] On January 3, 2020, the government received an additional 439.86 GB of Outlook 365 email data from 15 additional custodians (5 of whom were identified by defendant Balwani as a priority). The government is making every effort to produce responsive information from this batch by the week of January 13, 2020.

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The government is using all available resources to conduct an exhaustive search. Its methods are reasonable and will ensure a fair trial. The defendants' claims of prejudice do not withstand scrutiny nor do they answer the fundamental issue that FDA can only process data so fast. The government shares the Court's and the defendants' desire to expedite the process and is committed to doing that. For these reasons, the Court should grant the motion.

DATED: January 9, 2020

Respectfully submitted,

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by 28 U.S.C. § 515

/s/

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